

FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) Meeting

FDA White Oak Campus, Building 31, The Great Room (Rm. 1503)

White Oak Conference Center, Silver Spring, Maryland

February 22, 2012

MEETING ROSTER

DESIGNATED FEDERAL OFFICER (Non-Voting)

Paul T. Tran, R.Ph

Division of Advisory Committee and Consultant Management

Office of Executive Programs, CDER, FDA

ENDOCRINOLOGIC AND METABOLIC DRUGS ADVISORY COMMITTEE MEMBERS (Voting)

Erica H. Brittain, Ph.D.

Mathematical Statistician

Biostatistics Research Branch

National Institute of Allergy and Infectious Diseases
(NIAID), National Institutes of Health (NIH)

Bethesda, Maryland

David M. Capuzzi, M.D., Ph.D.

Professor of Medicine and Biochemistry

Thomas Jefferson University &

Lankenau Institute for Medical Research
Philadelphia, Pennsylvania

Eric I. Felner, M.D., MSCR

Associate Professor of Pediatrics

Division of Pediatric Endocrinology

Director, Pediatric Endocrinology Fellowship
Program

Emory University School of Medicine
Atlanta, Georgia

Edward W. Gregg, Ph.D.

Chief, Epidemiology and Statistics Branch

Division of Diabetes Translation

Centers for Disease Control and Prevention (CDC)
Atlanta, Georgia

Abraham Thomas, M.D., M.P.H., FACP (Chair)

Division Head, Endocrinology, Diabetes, Bone, and
Mineral Disorders

Henry Ford Hospital

Whitehouse Chair of Endocrinology

Detroit, Michigan

Lamont G. Weide, M.D., Ph.D., FACE

Chief, Diabetes & Endocrinology

Professor, Internal Medicine

University of Missouri - Kansas City

Truman Medical Centers, Diabetes Center

Kansas City, Missouri

ACTING INDUSTRY REPRESENTATIVE TO THE COMMITTEE (Non-Voting)

Mads F. Rasmussen, M.D., Ph.D.

(Acting Industry Representative)

Executive Director

Diabetes - Clinical Development and Research

Clinical Development, Medical and Regulatory
Affairs

Novo Nordisk Inc.

Princeton, New Jersey

FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) Meeting

FDA White Oak Campus, Building 31, The Great Room (Rm. 1503)

White Oak Conference Center, Silver Spring, Maryland

February 22, 2012

MEETING ROSTER (cont.)

TEMPORARY MEMBERS (Voting)

Kenneth D. Burman, M.D.

Chief, Endocrine Section
Washington Hospital Center
Washington, District of Columbia

Robert R. Clancy, M.D.

Professor of Neurology and Pediatrics
The University of Pennsylvania School of Medicine
The Children's Hospital of Philadelphia
Philadelphia, Pennsylvania

Melanie Coffin (Patient Representative)

Washington, District of Columbia

Janet D. Cragan, M.D., M.P.H.

National Center on Birth Defects and Developmental
Disabilities
Division of Birth Defects and Developmental
Disabilities, CDC
Atlanta, Georgia

Katherine M. Flegal, Ph.D.

Senior Research Scientist
Distinguished Consultant
National Center for Health Statistics, CDC
Hyattsville, Maryland

Allison B. Goldfine, M.D.

Assistant Director of Clinical Research
Joslin Diabetes Center, Research Division
Boston, Massachusetts

Jessica W. Henderson, Ph.D.

(Acting Consumer Representative)
Professor of Community Health Education
Division of Health and Physical Education
Western Oregon University
Monmouth, Oregon

Sanjiv Kaul, M.D.

Director, Fellowship Training Program in
Cardiovascular Diseases
Cedars-Sinai Heart Institute
Professor, David Geffen School of Medicine at UCLA
Division of Cardiology
Cedar Sinai Medical Center
Los Angeles, California

Michael S. Lauer, M.D., FACC, FAHA

Director
Division of Cardiovascular Sciences
National Heart, Lung, and Blood Institute
(NHLBI), NIH
Bethesda, Maryland

Elaine H. Morrato, Dr.PH., M.P.H., C.P.H.

Assistant Professor
Departments of Health Systems, Management &
Policy Clinical Pharmacy and Pediatrics
Assistant Director
Children's Outcomes Research Program
Anschutz Medical Campus
University of Colorado-Denver
Aurora, Colorado

FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) Meeting

FDA White Oak Campus, Building 31, The Great Room (Rm. 1503)

White Oak Conference Center, Silver Spring, Maryland

February 22, 2012

MEETING ROSTER (cont.)

TEMPORARY MEMBERS (Voting)

Sonja A., Rasmussen, M.D., M.S.

Deputy Director
Influenza Coordination Unit, CDC
Atlanta, Georgia

Robert J. Smith, M.D.

Professor of Medicine (Endocrinology)
Alpert Medical School of Brown University
East Providence, Rhode Island

Almut G. Winterstein, Ph.D.

Associate Professor
Pharmaceutical Outcomes & Policy (POP)
College of Pharmacy
Epidemiology & Biostatistics
College of Public Health and Health Professions
Gainesville, Florida

Michael A. Rogawski, M.D., Ph.D.

Professor and Chair, Department of Neurology
University of California, Davis
Sacramento, California

Myrlene A. Staten, M.D.

Senior Advisor, Diabetes Translational Research
Division of Diabetes, Endocrinology and Metabolism
National Institute of Diabetes and Digestive and
Kidney Diseases (NIDDK), NIH
Bethesda, Maryland

Susan Z. Yanovski, M.D.

Co-Director, Office of Obesity Research
Director, Obesity and Eating Disorders Program
NIDDK, NIH
Bethesda, Maryland

SPEAKER (Non-Voting)

Suzanne M. Gilboa, Ph.D.

National Center on Birth Defects and
Developmental Disabilities, CDC
Atlanta, Georgia

FDA PARTICIPANTS (Non-Voting)

John K. Jenkins, M.D.

Director
Office of New Drugs, CDER, FDA

Mary H. Parks, M.D.

Director
Division of Metabolism and Endocrinology Products
(DMEP)
Office of Drug Evaluation II (ODE II)
OND, CDER, FDA

FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) Meeting

FDA White Oak Campus, Building 31, The Great Room (Rm. 1503)

White Oak Conference Center, Silver Spring, Maryland

February 22, 2012

MEETING ROSTER (cont.)

Eric C. Colman, M.D.

Deputy Director

DMEP, ODE II, OND, CDER, FDA

Mary D. Roberts, M.D.

Clinical Reviewer

DMEP, ODE II, OND, CDER, FDA

Joyce Weaver, Pharm.D.

Senior Drug Risk Management Analyst

Division of Risk Management

Office of Medication Error Prevention and Risk
Management (OMEPRM)

Office of Surveillance and Epidemiology (OSE)

CDER, FDA

Claudia B. Karwoski, Pharm.D.

Director, Division of Risk Management

OMEPRM, OSE, CDER, FDA